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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,233	07/25/2001	Samuel J. Tremont	061765.00195	4337

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/912,233

Applicant(s)
TREMONT et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-263 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-263 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

Art Unit: 1624

DETAILED ACTION

Claims 1-263 are pending in the application.

Information Disclosure Statement

1. The information disclosure statement filed June 24, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.
2. It is also noted that the information disclosure statements filed November 19, 2002 and June 24, 2002 indicates that they are supplemental, however, there are no other information disclosure statements of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-263 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of "prodrug" is not adequately enabled. Applicants provide no guidance as

Art Unit: 1624

how the compounds are made more active *in vivo*. The choice of a “prodrug” will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-225, 230 and 237-263 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by the moiety oxo. Oxo is the moiety =O. There is no indication that the various moieties can possess a divalent moiety such as =O. See lines 13 and 19 on page 389, see line 11 on page 390, lines 7 and 21 on page 391, line 7 on page 392, lines 10 and 16 on page 393, line 12 on page 394, etc.
- b) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by polyalkyl. See line 19 on page 389, lines 8 and 16 on page 390, line 14 on page 391, lines 1, 12 and 25 on page 392, lines 8 and 16 on page 393, lines 2 and 4 on page 394, etc.
- c) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by polyether. See lines 2, 10 and 18 on page 390, see line 18

Art Unit: 1624

on page 391, lines 5 and 16 on page 392, lines 2, 9 and 17 on page 393, line 2 on page 394, etc.

- d) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by alkylammoniumalkyl. See line 3 on page 391, line 16 on page 391, line 4 and 15 on page 392, etc.
- e) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by the moiety sulfo. Sulfo is the moiety =S. There is no indication that the various moieties can possess a divalent moiety such as =S. See line 6 on page 392, etc.
- f) Claims 1-225, 251-254 and 257-261 are vague and indefinite in that it is not known what is meant by the moiety $-P^9R^{10}$. See line 10 on page 392, etc.
- g) Claims 1, 8, 9, 36, 37, 82, 83, 163, 184, 205 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definition of A which is a cation, however, A has a negative charge. See line 22 on page 392, etc.
- h) Claims 2, 3, 10, 11, 29-31, 38, 39, 75-77, 84, 85 and (claims dependent thereon) recite the limitation "anion" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- i) Claims 10, 11, 38, 39, 84, 85, 125, 145 and (claims dependent thereon) recite the limitation " $-SR^9$, $-S(O)_3R^9$ and $-N^+R^9R^{11}R^{12}A^-$ " in the definition of R^{13} , R^{14} and R^{15} . There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

- j) Claims 10, 11, 38, 39, 84, 85, 125, 145 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definition of R⁹ and R¹⁰ which includes the moiety carboxyalkylheterocycle which is a class of compounds not a substituent.
- k) Claims 10, 11, 38, 39, 84, 85, 125, 145 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the definition of R¹³, R¹⁴ and R¹⁵ which includes the moiety heterocycle which is a class of compounds not a substituent.
- l) Claims 14, 42, 88, 128, 148 and (claims dependent thereon) recite the limitation "phenylene" in the Moe in line 1 of page 412; in line 4 on page 438; in line 7 on page 467, etc. There is insufficient antecedent basis for this limitation in the claim.
- m) Claims 14, 42, 88, 128, 148 and (claims dependent thereon) recite the limitation "2-6-pyridinene" in the Moe in line 5 of page 412; in line 1 on page 439; in line 4 on page 468, etc. There is insufficient antecedent basis for this limitation in the claim.
- n) Claims 14 and (claims dependent thereon) recite the limitation "R where R is 1000 MW PEG" in the Moe in line 2 of page 413. There is insufficient antecedent basis for this limitation in the claim.
- o) Claims 14, 42, 88, 128, 148 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety in line 4 on page 413;

Art Unit: 1624

in line 5 on page 439; in line 2 on page 469, etc. which is missing a bond to the nitrogen atom adjacent to the sulfonyl.

- p) Claims 14, 42, 88 and (claims dependent thereon) recite the limitation "N(CH₂COOH)₂" in the Moe in line 4 of page 413; in line 5 on page 439; in line 2 on page 469, etc. There is insufficient antecedent basis for this limitation in the claim.
- q) Claims 14, 42, 88, 128 and 148 do not end with a period.
- r) Claims 29, 75 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moiety -O(CH₂)_{1,4}NR'R''R''' which contains a nitrogen atom with four bonds.
- s) Claims 121 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the last moiety on page 474.
- t) Claims 122 and (claims dependent thereon) recite the limitation "0" in the definition of p. There is insufficient antecedent basis for this limitation in the claim.
- u) Claims 141 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the nitrogen atom of the benzothiazepine ring which only has two bonds.
- v) Claims 142 and (claims dependent thereon) recite the limitation "0" in the definition of r. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1624

- w) Claims 169 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 1-6 on page 510; in lines 1-4 on page 511; in lines 1-4 and 6 on page 512; in line 5 on page 513 and in lines 1-3 on page 514 which have nitrogen atom(s) with only two bonds.
- x) Claims 169 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 1 on page 510 and in line 3 on page 512 which is lacking the carbonyl of the sugar.
- y) Claims 169 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 6 on page 510; in lines 2 and 3 on page 511; in line 1 on page 512; in lines 2, 4 and 5 on page 513 and in line 2 on page 514 which is lacking the $\text{-CH}_2\text{-OH}$ of the sugar.
- z) Claims 190 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 1-6 on page 523; in lines 1-4 on page 524; in lines 1-4 and 6 on page 525; in line 5 on page 526 and in lines 1-3 on page 527 which have nitrogen atom(s) with only two bonds.
- aa) Claims 190 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 1 on page 523 and in line 3 on page 525 which is lacking the carbonyl of the sugar.
- ab) Claims 190 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 6 on page 523; in lines 2 and 3 on

Art Unit: 1624

page 524; in line 1 on page 525; in lines 2, 4 and 5 on page 526 and in line 2 on page 527 which is lacking the $\text{-CH}_2\text{-OH}$ of the sugar.

- ac) Claims 211 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 1-6 on page 536; in lines 1-4 on page 537; in lines 1-4 and 6 on page 538; in line 5 on page 539 and in lines 1-3 on page 540 which have nitrogen atom(s) with only two bonds.
- ad) Claims 211 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 1 on page 536 and in line 3 on page 538 which is lacking the carbonyl of the sugar.
- ae) Claims 211 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 6 on page 536; in lines 2 and 3 on page 537; in line 1 on page 538; in lines 2, 4 and 5 on page 539 and in line 2 on page 540 which is lacking the $\text{-CH}_2\text{-OH}$ of the sugar.
- af) Claims 230 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 9-11 on page 544; in lines 1-5 on page 545; in lines 1-4 on page 546; in lines 1, 2 and 4 on page 547; in lines 4-5 on page 548; and in lines 1-2 on page 549 which have nitrogen atom(s) with only two bonds.

Art Unit: 1624

- ag) Claims 230 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 9 on page 544 and in line 1 on page 547 which is lacking the carbonyl of the sugar.
- ah) Claims 230 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 3 and 5 on page 545; in lines 1 and 3 on page 546; in lines 1, 3 and 4 on page 548; and in line 1 on page 549 which is lacking the $\text{-CH}_2\text{-OH}$ of the sugar.
- ag) Claims 237 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the nitrogen atom of the benzothiazepine ring which only has two bonds.
- ah) Claims 241 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 9-11 on page 552; in lines 1-5 on page 553; in lines 1-4 on page 554; in lines 1, 2 and 4 on page 555; in lines 4-5 on page 556; and in lines 1-2 on page 558 which have nitrogen atom(s) with only two bonds.
- ai) Claims 241 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in line 9 on page 552 and in line 1 on page 555 which is lacking the carbonyl of the sugar.
- aj) Claims 241 and (claims dependent thereon) are vague and indefinite in that it is not known what is meant by the moieties in lines 3 and 5 on page 553; in lines 1 and 3


Art Unit: 1624

on page 554; in lines 1, 3 and 4 on page 556; and in line 1 on page 557 which is lacking the $\text{-CH}_2\text{-OH}$ of the sugar.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday from 11:30 AM to 8:00 PM and on Thursday and Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
October 1, 2002